Standard Operating Procedure – Statistical Analysis Plan SOP

This cover sheet controls the layout and components of the entire document.

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Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	December 13, 2005	SOP WG Review	All pages	Document Creation
1.0	December 13, 2005	SOP WG Approval	All pages	Document Creation
1.0	January 10, 2006	BP SIG Approval	All pages	Document Creation
1.0	October 30, 2006	BP SIG/SOP WG	All pages	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the process for the development and maintenance of SOPs at intramural and extramural sites under the caBIG™ umbrella.

2. Scope

This SOP will be used as guidance for the development and maintenance of all SOPs related to: a) research covered under the caBIG™ Program and sponsored by the National Cancer Institute (NCI), and b) the sharing of data across caBIG™ participant sites, the regulatory community and commercial industry.

3. Requirements

3.1 The SAP is a clearly defined section within the protocol and approved prior to the start of clinical research study.

3.2 The SAP should include the details of the planned statistical analyses associated with a clinical study. The analyses are planned with the desired work product(s) in mind and should be conducted in a consistent and repeatable manner.

3.3 The SAP should contain the detailed requirements and parameters for the reporting results of the clinical research trial, the format and content of output reports, and the tests to support the robustness and sensitivity of the analysis conducted.

3.4 Recommended checks and specific procedures whose implementation and completion will improve/ensure the quality of the plan and the associated data, as well as prevent study compromise, should be included.

3.5 The SAP should include, at a minimum, for each Primary and Secondary Endpoint:

3.5.1 How the outcome will be measured.

3.5.2 Any transformations on the data likely to be required before analysis.

3.5.3 Appropriate statistical tests which will be used to analyze the data.

3.5.4 How missing data will be accounted for in the analyses (both scientifically and statistically).

3.5.5 Whether statistical inference will be drawn and if any statistical adjustments for multiple comparisons will be performed.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	CR-001	SOP for Study Setup
4.2	CR-002	SOP for Study Conduct
4.3	N/A	Guideline for Clinical Data Management Plan
4.4	N/A	ICH E3: Guideline, Structure and Content of Clinical Study Reports
4.5	N/A	ICH E9: Guideline, Statistical Principles for Clinical Trials

5. Roles & Responsibilities

Role	Responsibility
Study Statistician	• Ensure that the protocol and any amendments cover all relevant statistical issues clearly and accurately. • Review the CRFs to ensure that primary and secondary endpoints are collected and/or captured appropriately to satisfy analyses called for in the SAP, where applicable. • Work with clinical data manager to update study plan if the SAP changes and if those changes reflect changes to data collected during the conduct of the clinical research trial.
Clinical Study Team	• Provide input to the Study Statistician on the protocol and SAP.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for the SAP	This documents the processes for identifying the study design in the SAP under the caBIG™ umbrella.
2) Process Flow for the SAP	This document identifies the workflow activities, by role, for the steps identified in the SAP.